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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,301	10/22/2003	Paul G. Ritchie	IND 50CON	2253
27777	7590	11/17/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/691,301	Applicant(s) RITCHIE ET AL.	
	Examiner david shay	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 127-142 and 161-165 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 127-142 and 161-165 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

Claims 127-142 and 161-165 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 127 and 136 the exact meaning of the term “ storing primary data in a memory device associated with the delivery device prior to an energy application” is unclear. Applicant is his own lexicographer, and is construing this term to read over Chin et al when a reading of the Abstract of Chin et al clearly and undeniably shows such storage, as the term is understood by those having ordinary skill in the art. As applicant is his own lexicographer and as applicant is asserting that the term “ storing primary data in a memory device associated with the delivery device prior to an energy application” has some meaning which is contrary to that understood by those having ordinary skill in the art, and at the same time refuses to define what the term is intended to mean, thus the meaning thereof is sufficiently unclear to warrant a rejection on the basis of indefiniteness, as knowing only that the term means something other than what one of ordinary skill would clearly construe the term to mean does not allow one having ordinary skill to determine the metes and bounds of the claim with reasonable specificity. Further the exact meaning intended to be ascribed to the terms “ primary data” and “ suitability” in the claims is also unclear in view of applicants assertion that data such as power level calibration and maximum time of usage are not primary data and that assuming that disposable assemblies are not re-used somehow does not constitute primary data, and the determination of suitability, respectively.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 127, 131, 133, and 134 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chin et al.

Chin et al teach storing primary data (see Abstract and Figure 2, element 36), which includes delivery device operational parameters and the number of uses, for example; connecting the device to a generator (see Figure 1); communicates data to a microprocessor therein (see Figure 4); and determining the suitability of the device (see column 5, lines 2-5). It is noted that the recitation “the group including...” in claim 127 is an open ended group and thus includes any other data in addition to those data listed. If applicant requires a clearer explanation than the foregoing, it will be necessary for applicant to state specifically what claimed elements are absent from the reference, that examiner may point them out in more detail.

Claims 127-131, and 133-135 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Harman et al.

Harman et al teach storing primary data such as number of uses, number and power level of pulses delivered (energy limits from calibration parameters), total number of channels created (see Abstract) connecting the device to an energy generator (see Figure 8A); communicating the data to a microprocessor and determining the suitability of the device (see Figure 8A, element 108 and Figure 8B, element 110). The presence of a recognized security code allows the device to determine that the data is readable.

Claims 127, 132, 135-143, <sup>n</sup> and 161-165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harman et al in combination with Jackson et al. Harman et al teach a method such as claimed (as set forth above) except checking for an expiry date and determining energy monitoring limits (please note the lack of teaching of energy monitoring limits necessarily means

that other steps predicated thereon – e.g. indicating an error condition when energy delivery is outside the limits are also not contained therein). Jackson et al teach a method such as claimed except making the various determinations via a microprocessor. It would have been obvious to the artisan of ordinary skill to employ a microprocessor in the method of Jackson et al since this is a well known digital data comparator as taught by Harman et al and since the structure has no manipulative effect on the method and thus cannot be given great patentable weight, or, alternatively, to include the energy limits from calibration parameters; in the method of Harman et al, since this would provide increases patient safety by preventing the inadvertent setting of a power value which is more than the device was designed to handle, which could lead to catastrophic device failure during the surgical procedure, official notice of which has already been taken, and in either case to provide an expiry date, since this is not critical, provides no unexpected result, and would prevent the use of a device which is too old, thus producing a method such as claimed.

Applicant argues that Chin et al does not teach, “ storing primary data in a memory device associated with said delivery device prior to an energy application”. This is not convincing in view of Figure 4 of Chin et al.

With regard to the Harman et al reference the examiner has noted that the presence of a recognizable security code in the data of the security module indicates that since the security code data has not been corrupted, neither has the primary data. The systems determine that the device is suitable for delivery energy on the basis of e.g. its compatibility with the energy delivery device.

Applicant's arguments filed October 22, 2003 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

This is a Continuation of applicant's earlier Application No. 09/817,864. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader, can be reached on Monday, Tuesday, Thursday, and Friday

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at (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'David M. Shay', with a stylized flourish at the end.

DAVID M. SHAY  
PRIMARY EXAMINER  
GROUP 330